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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,952	11/21/2003	William D. Hitz	BB1077 US DIV	4183

23906 7590 07/14/2005

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,952

Applicant(s)

HITZ ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☒ Claim(s) 3,4,9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: _____

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 04/25/05 is acknowledged. The traversal is on the ground(s) that Applicant submits the nucleotide sequences of SEQ ID NO: 1, 15, 5 and 11 all encode soybean myo-inositol 1-phosphate synthase. Applicant states that there is only one nucleotide difference between SEQ ID NO: 1 and SEQ ID NO: 5, and between SEQ ID NO: 11 and 15, while the difference between SEQ ID NO: 1 and 11 is 42 nucleotides. Applicant asserts that the coexamination of SEQ ID NO: 1, 5, 11, and 15 would not be burdensome. These arguments have been considered and found persuasive since the search of SEQ ID NO: 1 and 11 will reveal arts relevant to SEQ ID NO: 5 and 15, respectively. SEQ ID NO: 5 and 11 are mutants that differ the wild-type SEQ ID NO: 1 and 11, respectively, by one nucleotide. Therefore, SEQ ID NO: 5, 11 and 15 are hereby rejoined with SEQ ID NO: 1. The requirement is made FINAL.

Claims 1-10 are pending and are examined.

Sequence Listing

Applicant's CRF and paper sequence listing filed 12/24/03 have been entered. However, this application fails to comply with the requirements of 37 CFR 1.821-1.825 because the sequence listings on page 35, lines 25 and 30; page 39, line 15; and page 40, line 15 of the specification are not identified by SEQ ID NO: Applicant is respectfully requested to identify the sequences or to submit a new Sequence Listing that comprises said sequences. See attached Notice to comply.

Claim Objections

At claims 2-5 and 8-10, ---of--- should be inserted before "SEQ ID NO:", for clarification.

Information Disclosure Statement

The information disclosure statement filed 11/21/03 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not have the correct application serial number. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid of SEQ ID NO: 1, 5, 11 and 15 and chimeric gene comprising said nucleic acids, does not reasonably provide enablement for all nucleic acid fragments encoding a soybean myo-inositol

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phosphate synthase including those are substantially similar to SEQ ID NO: 1, 5, 11 or 15 and the complement and subfragments thereof, and any nucleic acid fragment from any source encoding a mutant myo-inositol 1-phosphate having decreased capacity for synthesis of myo-inositol-1 phosphate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated nucleic acid fragment encoding a soybean myo-inositol 1-phosphate synthase and nucleic acids that are substantially similar to SEQ ID NO: 1, 5, 11, and 15 and the complement and chimeric genes comprising subfragments of said nucleic acids encoding the same, and any nucleic acid fragment from any source encoding a mutant myo-inositol 1-phosphate having decreased capacity for synthesis of myo-inositol-1 phosphate.

Applicant teaches the identification and isolation of nucleic acids encoding the soybean myo-inositol phosphate synthases of SEQ ID NO: 2, 6, 12 and 16 from soybean wild type and LR33 mutant plants.

Applicant has not taught nucleic acid fragments from any source encoding a mutant myo-inositol 1-phosphate having decreased capacity for synthesis of myo-inositol-1 phosphate, and nucleic acids that are substantially similar to SEQ ID NO: 1, 5, 11 and 15 and encoding a soybean myo-inositol 1-phosphate synthase. The specification defines "substantially similar" as nucleic acid fragments with one or more nucleotide base changes that retain the functional property of the nucleic acids or the protein encoded by said nucleic acids. However, the instant specification does not

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provide guidance for any modifications to the disclosed nucleic acid sequences that retain the functional properties of the nucleic acids and its encoded protein. Applicant has not described regions or domains in the disclosed sequences that are required to encode a functional wild-type or mutant myo-inositol 1-phosphate synthase.

The state of the art for isolation of cDNA or genomic clones with specific function is highly unpredictable. Significant guidance is required with respect to hybridization and wash that will allow specific isolation of the target genes from all natural sources including soybean. In the absence of specific guidance, undue trial and error experimentation would be required to screen through the vast number of soybean and non-soybean cDNA and genomic clones to identify those that encode a functional or mutant myo-inositol 1-phosphate synthase, and determine those with decreased capacity for the synthesis of myo-inositol-1 phosphate.

The working examples disclosed in the specification are limited to SEQ ID NO: 1, 5, 11 and 15. The disclosed functional and structural properties of these sequences cannot be extrapolated to all nucleic acid fragments from any source or to all nucleic acids from soybean including those that are substantially similar to SEQ ID NO: 1, 5, 11 and 15, absent further guidance.

Therefore, given the lack of sufficient guidance in the specification; the limited working examples; the nature of the invention; the state of the art and unpredictability as discussed above, the claimed invention is not enabled throughout the broad scope. See, *In re Wands* (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). See also *In re Fischer*, 166 USPQ 19 24 (CCPA 1970) where the court held the scope of the claims

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must bear a reasonable correlation with the scope of the enablement.

Written Description

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a multitude of nucleic acid fragments from any source encoding a multitude of mutant myo-inositol 1-phosphate synthase polypeptides including nucleic acid fragments encoding a soybean myo-inositol 1-phosphate synthase and nucleic acids that are substantially similar to SEQ ID NO: 1, 5, 11, and 15 and a multitude of subfragments thereof and encoding the same. The claims are also drawn to chimeric genes comprising said nucleic acids operably linked to regulatory sequences. In contrast, Applicant describes SEQ ID NO: 1, 5, 11, and 15 from soybean. These are genus claims.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no

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distinguishing information concerning its identity... Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes... does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA... Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function... does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus... a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of all nucleic acid fragments encoding a mutant myo-inositol 1-phosphate synthase. Applicant has not described core structural elements common to said nucleic acid fragments, and a review of the literature does not indicate that such structural elements are well known in

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the art. In addition, a substantial variation in structures and function are expected among the subfragment nucleic acids required for the construct of claims 5 and 6. Therefore, Applicant has not described a representative number of DNA of the genus claimed. Since Applicant has not described the DNA as broadly claimed, chimeric genes comprising said nucleic acid fragments are similarly not described.

Therefore, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Remarks

The claims are deemed free of the prior art of record.

Claims 3-4 and 9-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

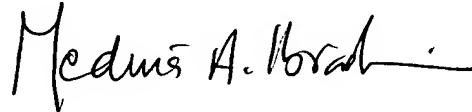
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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

7/11/05

Mai



MEDINA A. IBRAHIM
PATENT EXAMINER

Notice to Comply	Application No. 10/718,952	Applicant(s) Hitz et al	
	Examiner Medina A. Ibrahim	Art Unit 1638	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
 - ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
 - ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
 - ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
 - ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
 - ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
 - ☒ 7. Other: sequences on pages 35(lines 25 and30); page 39 (line 32); page 40 (line 15) are not identified by SEQIDNO.
- Applicant Must Provide:**
- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
 - ☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
 - ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510

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